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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/088,439 | 06/06/2002 | Michel Doare | 47890/MEG | 9155 |
| 23363 | 7590 | 01/11/2005 | EXAMINER | |
| CHRISTIE, PARKER & HALE, LLP PO BOX 7068 PASADENA, CA 91109-7068 | | | WEBB, SARAH K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,439

Applicant(s)

DOARE, MICHEL

Examiner

Sarah K Webb

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/13/02</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the specification should include headings for the separate parts of the disclosure, such as "Background of the Invention", "Summary of the Invention", "Brief Description of the Drawings", and "Description of the Invention." Appropriate correction is required.

Claim Objections

2. Claims 1-7 are objected to because of the following informalities: the reference numbers need to be removed from the claim language. For clarification, the different lumens should be given more descriptive labels that are not confusing. "Further lumen" and "additional lumen" are not clear. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a gate valve, does not reasonably provide enablement for the means by which the valve is opened. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification does not provide any structural

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characteristics of the valve or actuation means. It is unclear how the valve is actuated by a user.

4. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states, "*valve means that are assigned to the part of the additional lumen which ends on the proximal side of the proximal occlusion balloon.*" This is unclear, because this part of the lumen would only be the opening (15) in the disclosure. Applicant should state specifically where the valve is located. Regarding claim 3, the phrase "for instance" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 4 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,090,096 to St. Goar et al. in view of US Patent No. 6,165,196 to Stack et al.

Goar discloses a double balloon catheter used in bypass surgery (see column 11). As shown in Figure 8, the system includes a cannula (80) with two occlusion balloons (84, 110). Figure 9 shows all of the separate lumens of the cannula (80). Each balloon is connected to a separate inflation lumen (104, 112). An additional lumen (98) is connected to an extracorporeal blood supply device (55) and valve (63), which is illustrated in Figure 3B. The valve controls the lumen (98), which ends on the proximal side of the proximal balloon. This additional lumen

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opens (102) to the aorta proximal to the proximal balloon (84), but does not open distal to the distal balloon (110), as required by claim 1.

Stack discloses another double balloon catheter used in bypass and anastomosis procedures (column 3, lines 8-10). As shown in Figure 2, the catheter includes two balloons (16,18) connected to an inflation lumen (32) and an additional lumen (34) that has openings (26,28) both proximal to the proximal balloon and distal to the distal balloon. This additional lumen (34) allows blood to flow to the vessel on either side of the blocked anastomosis site created by the balloons (column 5, lines 34-43). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include openings to the additional lumen of Goar on the distal side of the distal balloon, as taught by Stack, as this allows the vessel distal to the blocked anastomosis site to be perfused during the surgical procedure.

Regarding claim 4, the cannula has another opening (96) between the occlusion balloons (84,110), wherein the opening (96) is connected to a separate lumen (92).

Regarding claims 5 and 6, Goar explains that the catheter may be pre-shaped to a curve, including exiting the aorta at a right angle (column 10, lines 28-35).

Goar discloses the method of using the catheter in column 8. The modified device meets the limitations of claims 8-20. Even though Goar does not explicitly state that anastomosis is performed, this is inherent to bypass surgery. Regarding claim 13, Goar explains that aspiration can be performed through the cardioplegic fluid delivery lumen by turning a valve (column 8, lines 31-35).

6. Claims 2 and 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Goar in view of Stack, as applied to claim 1 above, and further in view of US Patent No. 6,083,198 to Afzal.

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Regarding claim 2:

The modified Goar device fails to form the balloons to be moveable towards each other axially. Afzal discloses a double balloon catheter adapted for connection to an extracorporeal blood supply device during bypass surgery. The embodiment of the catheter in Figure 3 includes first and second balloons (35,37) that are movable towards one another by sliding inner and outer catheters (31,32) relative to one another (column 5, lines 18-24). Afzal teaches that this allows the catheter to be adapted to the size of many different patients (column 6, lines 30-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the balloons of the modified Goar device to be axially moveable, as Afzal teaches that this allows to the catheter to be adjusted according the size of the patient.

Regarding claim 3:

Goar includes a lumen 86 that supplies cardioplegic fluid to opening (90) that provokes cardiac arrest, but this lumen 86 opens distal the proximal balloon (84). Afzul teaches that cardioplegic fluid should be delivered proximal to the balloon (35) at opening (34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the simple modification to the Goar device to place the cardioplegic fluid delivery opening proximal to the proximal balloon, as Afzul teaches that this is another way to cause cardiac arrest with a catheter.

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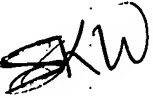
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhhuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
1/5/05



**JULIAN W. WOO
PRIMARY EXAMINER**